Go - Keto

User Manual

Blood Glucose & Ketone
Monitoring System



Incl. Masterclass + Facebook

Best choice for your keto journey

The most reliable Go-Keto meter

Go-Keto

Blood Glucose & Ketone Monitoring System

Self monitoring of blood glucose is an integral part of diabetes care, but the high cost of testing can make this impossible. Together, we can better manage your diabetes and help you live a longer and healthier life.

Welcome, and thank you for choosing the Go-Keto Blood Glucose & Ketone Monitoring System. The Go-Keto Blood Glucose & Ketone Monitoring System will give you accurate blood glucose or β-ketone (β-hydroxybutyrate) results from fresh whole blood samples in just a few simple steps.

To ensure accurate results from your Go-Keto Blood Glucose & Ketone Monitoring System, please follow these guidelines:

- Read instructions before use.
- Use the code chip that accompanies each box of test strips.
- Use only Go-Keto Blood Glucose Test Strips with the Go-Keto Blood Glucose & Ketone Meter to test your blood glucose concentration.
- Use only Go-Keto Blood Ketone Test Strips with the Go-Keto Blood Glucose & Ketone Meter to test your blood β-ketone concentration.
- For *in vitro* diagnostic use only. Your blood glucose & ketone monitoring system is to be used only outside the body for monitoring the effectiveness of diabetes control. It should not be used for the diagnosis of diabetes or diabetic ketoacidosis (DKA).
- For self-testing and professional use. For professional use, wear gloves to avoid contact with potentially hazardous biological specimens during testing.
- Test only whole blood samples with the Go-Keto Blood Glucose & Ketone Monitoring System.
- For self-testers, consult your physician or diabetes healthcare professional before making any adjustments to your medication, diet or activity routines.
- Keep out of reach of children.
- Keep this User's Manual in a safe place, do not discard it.
- Use the Go-Keto Blood Glucose & Ketone Meter according to the instruction. If not, the protection provided by the meter may be impaired.

By following the instructions outlined in this User's Manual, you will be able to use your Go-Keto Blood Glucose & Ketone Monitoring System to monitor your blood glucose and β-ketone, and better manage your diabetes, including diabetic ketoacidosis (DKA).

Table of Contents

Getting Started **1**

Component Descriptions 3

Blood Glucose & Ketone Meter 4

Meter Display 6

Blood Glucose Test Strips 9

Glucose Control Solution 12

Blood Ketone Test Strips 14

Ketone Control Solution 17

Installing the Battery **19**

Meter Setup Before Testing **20**

Step 1 – Coding the Meter 20

Step 2 – Adjusting the Meter Settings 22

Performing a Quality Control Test **27**

Glucose Quality Control Test 27

Ketone Quality Control Test 31

Testing Your Blood Glucose **35**

Step 1 – Getting a Drop of Blood 35

Step 2 – Testing Blood Glucose 41

"HI" and "LO" Messages 44

"Hypo" and "Hyper" Messages 45

"Ketone?" Message 45

Precautions and Limitations for Blood Glucose Testing 46

Testing Your Blood Ketone **47**

Step 1 – Getting a Drop of Blood 47

Step 2 – Testing Blood Ketone 49

"HI" Message 51

Precautions and Limitations for Blood Ketone Testing 52

Using the Meter Memory **53**

Viewing Stored Records 53

Clearing the Memory 55

Transferring Records 55

Maintenance **57**
Replacing the Battery 57
Caring for Your Go-Keto Blood Glucose & Ketone Monitoring System 58
Suggestion and Reference **59**
Suggested Blood Glucose Testing Time and Target Goals 59
Reference for Your β-Ketone Test Results 60
Comparing Meter and Laboratory Results **61**
Troubleshooting Guide **62**
Specifications **64**
Warranty **65**
Index of Symbols **66**
Index **67**

Getting Started

Before testing, read the instructions carefully and learn about all the components of your Go-Keto Blood Glucose & Ketone Monitoring System. Depending on the Go-Keto kit you purchase, some of the components may need to be purchased separately. Please check the list of contents on the outer box for details on which components are included with your purchase.



GO-Keto
Blood Glucose & Ketone Meter



Sterile Lancet



Clear Cap



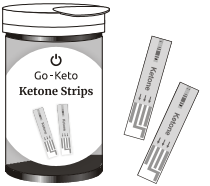
Lancing Device



Carrying Case



Go-Keto Blood Glucose Test Strips



Go-Keto Blood Ketone Test Strips



Go-Keto Glucose Code Chip



Go-Keto Ketone Code Chip



Go-Keto Glucose Control Solution



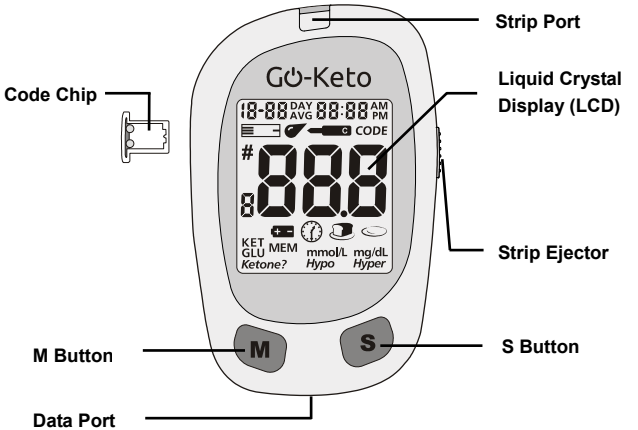
Go-Keto Ketone Control Solution

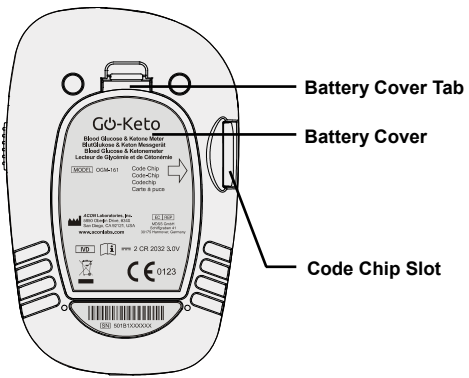
Component Descriptions

1. Meter: Reads the test strips and displays the blood glucose or β-ketone concentration.
2. Test Strips: Strips with a chemical reagent system used with the meter to measure glucose or β-ketone concentration in blood.
3. Code Chip: Automatically calibrates the meter with the code number when inserted into the meter.
4. Lancing Device: Used with sterile lancets for blood sample collection. The packaged lancing device has multiple depth settings, allowing users to adjust the depth of the puncture and minimize discomfort. It can also eject the used lancets.
5. Clear Cap: Used with the lancing device and sterile lancet to draw a blood sample from the forearm and palm.
6. Sterile Lancets: Used with the lancing device to draw a blood sample. Sterile lancets are inserted into the lancing device with each blood draw and discarded after use.
7. Control Solution: Verifies the proper operation of the monitoring system by checking the test strips and meter against a pre-calibrated control solution. Control Solution 1 is all you need most of the time. If you want to do additional levels of tests, Control Solution 0 and Control Solution 2 are available.
8. Carrying Case: Provides portability for blood glucose or β-ketone testing wherever you go.
9. User's Manual: Provides detailed instructions on using your Go-Keto Blood Glucose & Ketone Monitoring System.
10. Quick Reference Guide: Provides a brief overview of your Go-Keto Blood Glucose & Ketone Monitoring System and testing procedures. This small guide can be kept in your carrying case.
11. Warranty Card: Should be completed and returned to the distributor to qualify for the 5-year meter warranty.

Blood Glucose & Ketone Meter

The Go-Keto Blood Glucose & Ketone Meter is designed for use with the Go-Keto Blood Glucose Test Strips to test your blood glucose concentration and for use with the Go-Keto Blood Ketone Test Strips to test your blood β-ketone concentration. Use this diagram to become familiar with all the parts of your meter.





Liquid Crystal Display (LCD): Shows your test results, and helps you through the testing process.

M Button: Recalls previous test results from the meter memory and performs other menu selection functions.

S Button: Selects meter settings and performs other menu selection functions.

Strip Port: Test strips are inserted into this area to perform a test.

Strip Ejector: Slide the ejector forward to discard the used test strip.

Note: Dispose of blood samples and materials carefully. Treat all blood samples as if they are infectious materials. Follow proper precautions and obey all local rules when disposing of blood samples and materials.

Battery Cover: Remove the battery cover to install two CR2032 coin cell batteries.

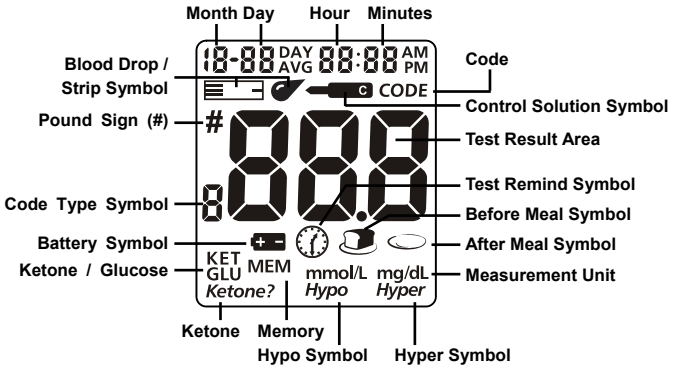
Battery Cover Tab: Press the battery cover tab to open battery cover.

Code Chip Slot: Insert the code chip.

Code Chip: For coding the meter. A new code chip comes with every box of test strips.

Data Port: Sends information to a computer via an optional data transfer cable to view, analyze and print stored data in the meter. The data transfer cable is available for order as an optional add-on.

Meter Display



Blood Drop / Strip Symbol: There two symbols appear at the same time to tell you when to apply the sample.

Pound Sign (#): Appears with the control solution test result or when you mark an invalid blood glucose test result to prevent it from being included in the average.

Code Type Symbol: Shows the code type of blood glucose test strips. “H” indicates the code number displayed is for Go-Keto blood glucose test strips.

Battery Symbol: Warns when you should replace the battery.

Ketone / Glucose: “KET” indicates a code number of ketone test strips or a blood β-ketone test result. “GLU” indicates a blood glucose test result. These two symbols will never appear at the same time.

Control Solution Symbol: Indicates a control test result. A pound sign (#) will also be displayed when control solution symbol appears.

Test Result Area: Indicates code number and test result.

Measurement Unit: Only one unit of blood glucose concentration will be displayed on your meter and cannot be adjusted.

Before Meal Symbol: Appears when before-meal test results are displayed.

After Meal Symbol: Appears when after-meal test results are displayed.

Test Remind Symbol: Appears to remind you to test your blood.

Hyper Symbol: Appears when the blood glucose concentration is above the “Hyperglycemia” (high blood sugar) target level that you have set.

Hypo Symbol: Appears when the blood glucose concentration is below the “Hypoglycemia” (low blood sugar) target level that you have set.

Ketone: Appears when the blood glucose concentration is above 16.7 mmol/L (300 mg/dL). A ketone test is recommended when this symbol appears. Consult your healthcare professional about testing for ketones.

Note: This symbol does not mean that the system has detected ketones. It simply recommends that a ketone test should be taken.

CODE: Appears with the code number of the test strips.

MEM: Shows a test result stored in memory.

Meter Use and Precautions

- The meter is pre-set to display blood glucose concentration in either millimoles per liter (mmol/L) or milligrams per deciliter (mg/dL) depending on which unit of measure is standard in your country. This unit of measure cannot be adjusted.
- The meter is pre-set to display blood β-ketone concentration only in millimoles per liter (mmol/L).
- Do not get water or other liquids inside the meter.
- Keep the strip port area clean.
- Keep your meter dry and avoid exposing it to extremes in temperature or humidity. Do not leave it in your car. Please use the meter indoor.
- Do not drop the meter or get it wet. If you do drop the meter or get it wet, check the meter by running a quality control test. Refer to **Quality Control Test** on page **27** for instructions.
- Do not take the meter apart. Taking the meter apart will void the warranty.
- Refer to the **Caring for Your Meter** section on page **58** for details on cleaning the meter.
- Keep the meter and all associated parts out of reach of children.

Note: Follow proper precautions and all local regulations when disposing of the meter and used batteries.

All Glucose systems preventive warnings with regard to EMC

1. This instrument is tested for immunity to electrostatic discharge as specified in IEC 61000-4-2. However, use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets, etc.) may cause damaging static discharges that may cause erroneous results.
2. This instrument complies with the emission and immunity requirements described in EN61326-1 and EN61326-2-6. Do not use this instrument in close proximity to sources of strong electromagnetic radiation. It may interfere with proper operation of the meter.
3. For professional use, the electromagnetic environment should be evaluated prior to operation of this device.

Blood Glucose Test Strips

The Go-Keto Blood Glucose Test Strips can work with the Go-Keto Blood Glucose & Ketone Meter to measure the glucose concentration in your whole blood.

The Go-Keto Blood Glucose Test Strips are thin strips with a chemical reagent system. After the strip is inserted into the meter, blood is applied to the sample tip of the test strip. The blood is then automatically absorbed into the reaction cell. A reaction takes place, and a transient electrical current is formed. The blood glucose concentration is calculated based on the electrical current detected by the meter. The result is shown on the meter display. The meter is calibrated to display plasma-like concentration results.

Sample Tip

Apply blood or control solution here.



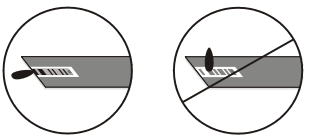
Check Window

Check to confirm that a sufficient sample has been applied.

Contact Bars

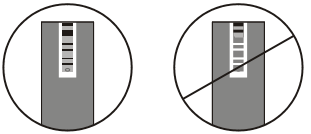
Insert this end of the test strip into the meter until it stops.

IMPORTANT: Apply sample only to the sample tip of the test strip. Do not apply blood or control solution to the top of the test strip as this may result in an inaccurate reading.



Correct **Incorrect**

Hold the blood drop to the sample tip of the test strip until the check window is completely full and until the meter begins to count down. If you applied a blood, but meter does not start to count down, you may reapply a second drop of blood within 3 seconds. If the check window does not fill and meter starts to countdown, then do not add more blood to the test strip. If you do then you may get an E-5 message or an inaccurate test result. In this case if the meter begins to countdown and check window does not fill, discard the strip and begin the test again with a fresh test strip.



Correct **Incorrect**

Code Number

Each package of blood glucose test strips is printed with a code number (CODE), lot number (LOT), unopened expiration date (⌛) and control range.

Storage and Handling

Please review the following storage and handling instructions:

- Store blood glucose test strips in a cool, dry place at 2-30ºC (36-86°F). Store them away from heat and direct sunlight.
- Do not freeze or refrigerate.
- Do not store or use test strips in a humid place such as a bathroom.
- Do not store the meter, the test strips or control solution near bleach or cleaners that contain bleach.
- Replace the cap on the test strip vial immediately after removing a test strip.
- The test strip should be used immediately after removing it from container.
- Do not use your test strips past the unopened expiration date printed on the label. Using test strips past the unopened expiration date may give incorrect test results.

  Note: The expiration date is printed in Year-Month-Date format.

Special instructions for blood glucose test strip in the vial

- Test strips should be stored in their tightly capped protective vial to keep them in good working condition.
- Do not store test strips outside their protective vial. Test strips must be stored in the original vial with the cap tightly closed.
- Do not transfer test strips to a new vial or any other container.
- Replace the cap on the test strip vial right away after removing a test strip.
- A new vial of blood glucose test strips may be used for 6 months after first being opened. Write the opened expiration date on the vial label after opening. Discard the vial 6 months after you first open it. Usage after this period may result in inaccurate readings.

Special Instructions for blood glucose test strip in foil pouch

- Tear the pouch carefully starting from the tear gap. Avoid damaging or bending the test strip.
- Use test strip immediately after removing it from the pouch.

Blood glucose test Strip Precautions

- For *in vitro* diagnostic use. Test strips are to be used only outside the body for testing purposes.
- Do not use test strips that are torn, bent, or damaged in any way. Do not reuse test strips.
- Before running a blood glucose test, make sure that the code number on the meter display matches the number shown on the blood glucose test strip vial or on the pouch.
- Keep the test strip vial or the foil pouch away from children and animals.
- Consult your physician or healthcare professional before making any changes in your treatment plan based on your blood glucose test results.

See the Go-Keto Blood Glucose Test Strips insert for more details.

Glucose Control Solution

The Go-Keto Glucose Control Solution can be used for a glucose quality control test.



Go-Keto
Glucose Control Solution

The Go-Keto Glucose Control Solution contains a known concentration of glucose. It is used to confirm that your meter and glucose test strips are working together properly and that you are performing the glucose test correctly. It is important to run a glucose quality control test regularly to make sure you are getting correct glucose test results.

You should run a glucose quality control test:

- Before you first use your meter to test blood glucose, to familiarize yourself with its operation.
- Before using a new box of blood glucose test strips.
- When you suspect that the meter or blood glucose test strips are not working properly.
- When you suspect that your blood glucose test results are inaccurate, or if they are inconsistent with how you feel.
- When you suspect your meter is damaged.
- After cleaning your meter.
- At least once a week.

Refer to **Glucose Quality Control Test** on page **27** for instructions on running a glucose quality control test.

Storage and Handling

Please review the following storage and handling instructions:

- Store the glucose control solution at 2-30°C (36-86°F).
- Do not refrigerate or freeze.
- If the control solution is cold, do not use until it has warmed to room temperature.
- Use before the unopened expiration date that is shown on the bottle.
  Note: The expiration date is printed in Year-Month-Date format.
- Each bottle of glucose control solution can be used for 6 months after first opened. Record the opened expiration date on the bottle label.

Glucose Control Solution Precautions

- For *in vitr*o diagnostic use. The glucose control solution is for testing only outside the body. Do not swallow or inject.
- Shake well before using.
- Glucose control solution tests are specified to be accurate only when tested between 10 and 40°C (50-104°F).
- The control ranges shown on the blood glucose test strip vial or on the foil pouch are not recommended ranges for your blood glucose level. Your personal blood glucose target ranges should be determined by your healthcare professional.
- Do not touch the test strip with the tip of the control solution bottle.
- Use the Go-Keto Glucose Control Solution with Go-Keto Blood Glucose Test Strips to perform a quality control test.

See the Go-Keto Glucose Control Solution insert for more details.

Blood Ketone Test Strips

The Go-Keto Blood Ketone Test Strips are thin strips with a chemical reagent system which can work with the Go-Keto Blood Glucose & Ketone Meter to measure the β-ketone concentration in your whole blood. After the strip is inserted into the meter, blood is applied to the sample tip of the test strip. The blood is then automatically absorbed into the reaction cell. A reaction takes place, and a transient electrical current is formed. The blood β-ketone concentration is calculated based on the electrical current detected by the meter. The result is shown on the meter display. The meter is calibrated to display plasma-like concentration results.

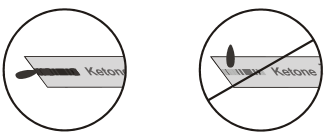
Sample Tip
Apply blood or control solution here.



Check Window
Check to confirm that a sufficient sample has been applied.

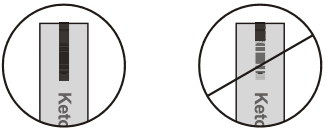
Contact Bars
Insert this end of the test strip into the meter until it stops.

IMPORTANT: Apply sample only to the sample tip of the test strip. Do not apply blood or control solution to the top of the test strip as this may result in an inaccurate reading.



Correct **Incorrect**

Hold the blood drop to the sample tip of the test strip until the check window is completely full and until the meter begins to count down. If you applied a blood, but meter does not start to count down, you may reapply a second drop of blood within 3 seconds. If the check window does not fill and meter starts to countdown, do not add more blood to the test strip. If you do then you may get an E-5 message or an inaccurate test result. In this case if the meter begins to countdown and check window does not fill, discard the strip and begin the test again with a fresh test strip.



Correct **Incorrect**

Code Number



Each package of Go-Keto Blood Ketone Test Strips is printed with a code number (CODE), lot number (LOT), unopened expiration date (⌛) and control range (CTRL0, CTRL1 and CTRL 2).

Storage and Handling

Please review the following storage and handling instructions:

- Store Go-Keto Blood Ketone Test Strips in a cool, dry place, 5-30ºC (41-86°F). Store them away from heat and direct sunlight.
- Do not freeze or refrigerate.
- Do not store or use test strips in a humid place such as a bathroom.
- Do not store the meter, the test strips or control solution near bleach or cleaners that contain bleach.
- Replace the cap on the test strip vial immediately after removing a test strip.
- The test strip should be used immediately after removing it from container.
- Do not use your test strips past the unopened expiration date printed on the label. Using test strips past the unopened expiration date may give incorrect test results.
  Note: The expiration date is printed in Year-Month-Date format.

Special instructions for blood ketone test strip in the vial

- Test strips should be stored in their tightly capped protective vial to keep them in good working condition.
- Do not store test strips outside their protective vial. Test strips must be stored in the original vial with the cap tightly closed.
- Do not transfer test strips to a new vial or any other container.
- Replace the cap on the test strip vial right away after removing a test strip.
- A new vial of test strips may be used for 6 months after first being opened. Write the opened expiration date on the vial label after opening. Discard the vial 6 months after you first open it. Usage after this period may result in inaccurate readings.

Special Instructions for blood ketone test strip in foil pouch

- Tear the pouch carefully starting from the tear gap. Avoid damaging or bending the test strip.
- Use test strip immediately after removing it from the pouch.

Blood Ketone Test Strip Precautions

- For *in vitro* diagnostic use. Test strips are to be used only outside the body for testing purposes.
- Do not use test strips that are torn, bent, or damaged in any way. Do not reuse test strips.
- Before running a blood β-ketone test, make sure that the code number on the meter display matches the number shown on the test strip vial or on the foil pouch.
- Keep the test strip vial or the foil pouch away from children and animals.
- Consult your physician or healthcare professional before making any changes in your treatment plan based on your blood β-ketone test results.

See the Go-Keto Blood Ketone Test Strips insert for more details.

Ketone Control Solution

The Go-Keto Ketone Control Solution contains a known concentration of β-ketone. It is used to confirm that your Go-Keto Blood Glucose & Ketone Meter and Go-Keto Blood Ketone Test Strips are working together properly and that you are performing the test correctly. It is important to run a ketone quality control test to make sure you are getting correct blood β-ketone test results.

You should run a ketone quality control test:

- Before you first use your meter to test blood β-ketone, to familiarize yourself with its operation.
- Before using a new box of Go-Keto Blood Ketone Test Strips.
- When you suspect that the Go-Keto Blood Glucose & Ketone Meter or Go-Keto Blood Ketone Test Strips are not working properly.
- When you suspect that your blood β-ketone test results are inaccurate, or if they are inconsistent with how you feel.
- When you suspect your meter is damaged.
- After cleaning your meter.



Refer to **Ketone Quality Control Test** on page **31** for instructions on running a ketone quality control test.

Storage and Handling

Please review the following storage and handling instructions:

- Store the Go-Keto Ketone Control Solution at 5-30°C (41-86°F).
- Do not refrigerate or freeze.
- If the control solution is cold, do not use until it has warmed to room temperature.
- Use before the unopened expiration date that is shown on the bottle.

  Note: The expiration date is printed in Year-Month-Date format.
- Each bottle of Go-Keto Ketone Control Solution can be used for 6 months after first opened. Record the opened expiration date on the bottle label.

Ketone Control Solution Precautions

- For *in vitro* diagnostic use. The control solution is for testing only outside the body. Do not swallow or inject.
- Shake well before using.
- The tests with Go-Keto Ketone Control Solution are specified to be accurate only when tested between 10 and 40°C (50-104°F).
- The control ranges shown on the test strip vial or on the foil pouch are not recommended ranges for your blood β-ketone level. Consult with your healthcare professional for the blood β-ketone range that is appropriate for you.
- Do not touch the test strip with the tip of the control solution bottle.
- Use only the Go-Keto Ketone Control Solution with Go-Keto Blood Ketone Test Strips to perform a ketone quality control test.

See the Go-Keto Ketone Control Solution insert for more details.

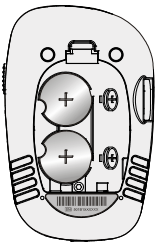
Installing the Battery

Battery may not be preinstalled in the meter. Two CR 2032 3.0V coin cell batteries are required. Please find the batteries in your carrying case and install them according to the following steps:

1. Turn over the meter to locate the battery cover. Press the battery cover tab on the top and lift the cover to open it.



2. Insert two new CR 2032 3.0V coin cell batteries on top of the plastic tape. Make sure it is aligned with the plus (+) side facing up in the battery carrier.



3. Close the battery cover and make sure that it snaps shut.

Meter Setup Before Testing

Before testing, the following steps should be followed:

Step 1 – Coding the Meter

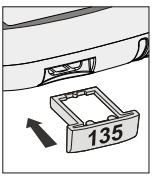
Every time you change to a new box of test strips, you need to insert the code chip packed with the new box of test strips.

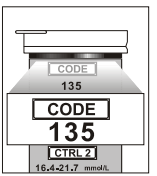
Coding the meter before using a new box of blood glucose test strips

1. Take the glucose code chip from the blood glucose test strip box. Check the letter printed on the side of the glucose code chip. “H” indicates a Go-Keto glucose code chip. Make sure to use the same brand of glucose code chip and blood glucose test strips. If the brand of the code chip packaged with the test strips is not correct, please contact your local distributor immediately.



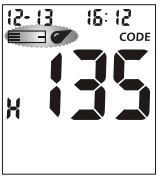
2. Compare the code number on the code chip with the code number printed on the test strip vial label (or on the foil pouch). If the two numbers are not the same, you may get inaccurate results. If the code number on the code chip does not match the number on the vial (or on foil pouch) of strips with which it was packaged, please contact your local distributor immediately.
3. With your meter turned off, insert the new glucose code chip into the code chip slot of the meter. It should easily snap into place. The code chip should remain in the meter, do not take it out until you change to another new box of test strips.





4. Turn the meter on by inserting a blood glucose test strip. You can see the code appear on the center of the screen. And then the code is stored in the meter automatically. The code for Go-Keto Blood Glucose Test Strips starts with “H”.

If the code on the code chip does not match the code that is displayed on the screen, please contact your local distributor immediately.

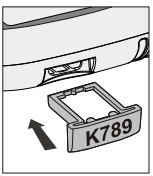


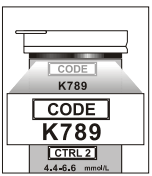
Note: The most recently used glucose code will be stored in the meter as a default glucose code for the rest of your blood glucose tests, until you insert a new glucose code chip into the meter.

5. If a blood glucose test strip is inserted and no glucose code is stored in memory, the display will flash "- - -" and "CODE".

Coding the meter before using a new box of blood ketone test strips

1. Take the ketone code chip from the blood ketone test strip box. The code for blood ketone test strips starts with "K". Compare the code on the ketone code chip with the code printed on the test strip vial label (or on the foil pouch). If the two codes are not the same, you may get inaccurate results. If the code on the ketone code chip does not match the one on the vial (or on foil pouch) of strips with which it was packaged, please contact your local distributor immediately.
2. With your meter turned off, insert the new ketone code chip into the code chip slot of the meter. It should easily snap into place. The code chip should remain in the meter, do not take it out until you change to another new box of test strips.





3. Turn the meter on by inserting a blood ketone test strip. You can see the code number and the "KET" symbol appear on the center of the screen. And then the ketone code is stored in the meter automatically. If the code number on the ketone code chip does not match the number that is displayed on the screen, please contact your local distributor immediately.

Note: The most recently used ketone code will be stored in the meter as a default ketone code for the rest of your blood β-ketone tests, until you insert a new ketone code chip into the meter.

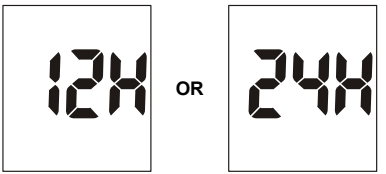
4. If a blood ketone test strip is inserted and no ketone code is stored in memory, the display will flash "- - -" and "CODE".

Step 2 – Adjusting the Meter Settings

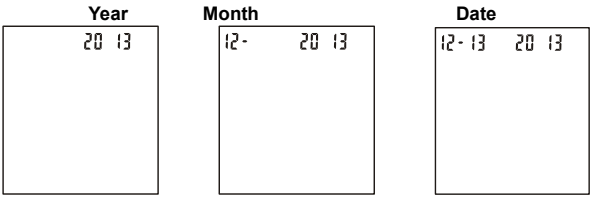
Before using your meter for the first time, you will need to adjust the settings that are listed in detail below.

1. Meter Setup Mode: Press the S button for 2 seconds to enter the meter setup mode. The meter will automatically enter the setup mode when turned on for the first time by any method.
2. Clock: Set the clock for either 12 or 24 hour mode. Press the M button to switch between the two settings. Then press the S button to save your choice and then start setting the year, month and date.

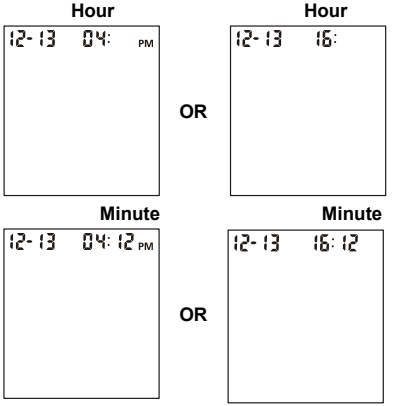
   Note: The clock needs to be reset after replacing the battery.



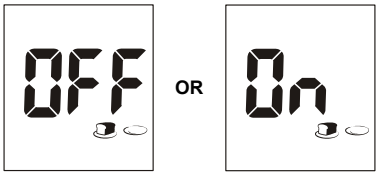
3. Date: The year will appear at the top of the display. Press the M button until the correct year is displayed. Once you have selected the correct year, press the S button to save your choice and start setting the month. Press the M button until the correct month is displayed. Then press the S button to save your choice and start setting the date. Press the M button until the correct date is displayed. Then press the S button to save your choice and start setting the time.



4. Time: The hour will appear at the top of the display. Adjust the hour with the M button until the correct hour is displayed. Press the S button to save your choice and set the minutes. Press the M button to change to the correct minute. Press the S button to save your choice and move to set the meal marker feature.



5. Meal Marker: The meter comes with the meal marker feature disabled. The meter shall allow the user to enable or disable the meal marker option. The words “On” or “Off” will be displayed on the large center segments of the display. The symbol of “before meal” and “after meal” will be displayed as shown below.



Press the M button to switch between turning the meal marker “On” and “Off”. Press the S button to confirm your selection.

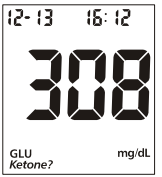
6. Audio Feature: The meter comes with the meter audio feature enabled. The meter will give one short beep when it is turned on, after sample detection and when the result is ready. The meter will sound three short beeps to sound a warning when an error has occurred. Please check the error number on the display to confirm what kind of error has occurred.



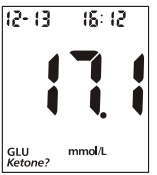


Press the M button to switch between turning the meter beep “On” and “Off”. Press the S button to confirm your selection.

7. Ketone Indicator: The meter comes with the Ketone indicator feature disabled. Press the M button to switch between turning the Ketone indicator “On” and “Off”. Press the S button to confirm your selection. When the Ketone indicator is enabled, if the test result is higher than 16.7 mmol/L (300 mg/dL), the symbol of "Ketone?" will appear on the display.



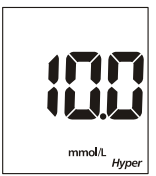
OR



8. Hyper Indicator: The meter comes with the Hyper indicator feature disabled. Press the M button to switch between turning the Hyper indicator “On” and “Off”. Press the S button to confirm your selection. When the Hyper indicator is “Off”, pressing the S button will go to the next Hypo indicator set up. When the Hyper indicator is “On”, pressing the S button will go to the Hyper indicator level set up. At the Hyper level set up, press the M button to adjust the Hyper level then press the S button to go to the Hypo indicator set up.

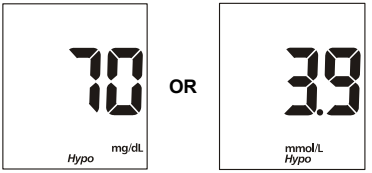


OR



Note: The meter allows the hyperglycemia level to be as low as 6.7 mmol/L (120 mg/dL) or higher. The hyperglycemia level should be above the hypoglycemia level. Consult your healthcare professional before determining what your hyper blood glucose level is.

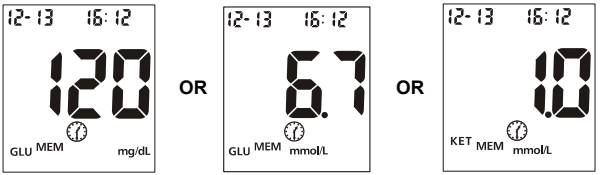
9. Hypo Indicator: The meter comes with the Hypo indicator feature disabled. Press the M button to switch between turning the Hypo indicator “On” and “Off”. Press the S button to confirm your selection. When the Hypo indicator is “Off”, pressing the S button will go to the Test Reminder set up. When the Hypo indicator is “On”, pressing the S button will go to the Hypo indicator level set up. At the Hypo level set up, press the M button to adjust the Hypo level then press the S button to go to the Test Reminder set up.



Note: The meter allows the hypoglycemia level to be as high as 5.6 mmol/L (100 mg/dL). The hyperglycemia level should be above the hypoglycemia level. Consult your healthcare professional before determining what your hypo blood glucose level is.

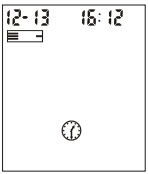
10. Test Reminder: Test reminder is a useful way to remind you when to test. You can set 1 to 5 reminders per day. Your meter is preset with the test reminder disabled. You must turn it on to use this feature.
    - Press the M button to switch between turning the first Test Reminder “On” and “Off”. Press the S button to confirm your selection. When the Test Reminder is “Off”, pressing the S button will go to the set up of the second Test Reminder. When the Test Reminder is “On”, pressing the S button will go to the set up of the time for the first Test Reminder. Press the M button to adjust the first Test Reminder time. (Time is adjusted by every minutes.) Press the S button to confirm the first Test Reminder time and then go to the second Test Reminder set up.
    - When the Test Reminder is “Off” during the second Test Reminder set up, pressing the S button will go to the set up of the third Test Reminder. When the Test Reminder is “On”, pressing the S button will go to the set up of the time for the second Test Reminder. Press the M button to adjust the second Test Reminder time. (Time is adjusted by every minutes.) Press the S button to confirm the second Test Reminder time and then go to the third Test Reminder set up.
    - Repeat the same set up procedure for Test Reminder 3, 4 and 5.
    - After finishing the fifth Test Reminder set up, it will then end the setup mode and power off the meter.

If one or more test reminders have been set, the reminder symbol will always appear on the LCD screen when the meter is turned on. The display sample is shown below.



The meter beeps 5 times at the time you set, again two minutes later, and two minutes after that unless you insert a test strip or press any button. This function will still work with Audio feature turned off.

When the meter beeps at the time set by the Test Reminder feature, the date, time and strip symbol will be displayed. And the Test Reminder symbol will be flashed. The display sample is shown below.



NOTE:

- The “Meal Marker”, “Ketone Indicator” and “Hyper/Hypo Indicator” are only for indicating blood glucose test results.
- For any step of the set up, if the M button is pressed and held, it will allow a faster adjustment.
- The user can press and hold the S button for 2 seconds to stop the set up and turn off the meter during any step of the set up process, except when setting up the year, date and time for the first time after installing a new battery.

Performing a Quality Control Test

The quality control test confirms that the test strips and meter are working together properly, and that you are performing the test correctly.

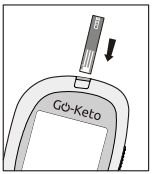
Glucose Quality Control Test

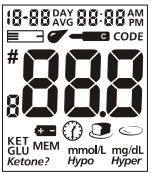
The Go-Keto Glucose Control Solution can be used for a glucose quality control test.

You should run a glucose quality control test:

- Before you first use your meter to test blood glucose, to familiarize yourself with its operation.
- Before using a new box of glucose test strips.
- When you suspect that the meter or blood glucose test strips are not working properly.
- When you suspect that your blood glucose test results are inaccurate, or if they are inconsistent with how you feel.
- When you suspect your meter is damaged.
- After cleaning your meter.
- At least once a week.

1. Insert a Go-Keto blood glucose test strip into the strip port, contact bars end first and facing up. (Insert the strip in as far as it will go without forcing.) This will turn on the meter and display all the display segments. If the audio option is on, the meter will beep, signaling the meter is turned on.





2. Check the display to confirm that all the display segments turn on (see display illustration above).
3. Following this display check, the system will enter the test mode. The display will show the date, time and the strip icon with the blood sample icon blinking. The code type and code number will be displayed in the center of the screen.

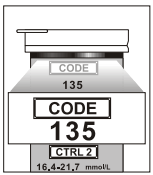


Compare the code type letter before the code number on the display with the brand of the strip inserted in the meter. “H” is for a Go-Keto Blood Glucose Test Strip. If the code type on the display does not match the brand of the strip inserted in the meter, please make sure to locate and insert the correct code chip that came with the box of blood glucose test strips.

Make sure that the code number that appears on the display matches the code number (CODE) on the test strip vial (or on foil pouch). If not, make sure to locate and insert the code chip that came with the box of blood glucose test strips.





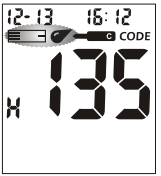


Do not perform a test if the codes still do not match. You will need a new package of test strips to perform a test.

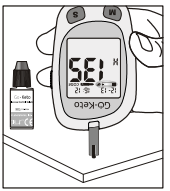
The blinking test strip and blood drop icon indicates that the test strip is inserted correctly.

Note: If the test strip has been inserted incorrectly, the meter will not turn on.

4. Press the M button to mark the test as a control solution test. The control solution symbol will appear on the display once the M button is pressed. Then a drop of glucose control solution can be added.



5. Shake the glucose control solution bottle well, then squeeze it gently and discard the first drop. If the tip clogs, tap the tip gently on a clean, hard surface, then shake again and use. Squeeze out a second small drop on a clean nonabsorbent surface. Touch the sample tip of the test strip to the control solution drop. If the audio option is turned on, the meter will beep indicating a test has been started.



Note:

- Do not apply control solution to the test strip directly from the bottle.
- If you applied the control solution sample but do not see the starting of the count down, you may reapply a second drop within 3 seconds.

6. Once a sufficient sample has been applied, then the meter display will count down from 5 to 1 and then display the blood glucose test result. The glucose control solution test results should be within the control range printed on the blood glucose test strip vial (or on foil pouch). This means that your blood glucose monitoring system is working properly and that you are performing the procedure correctly.

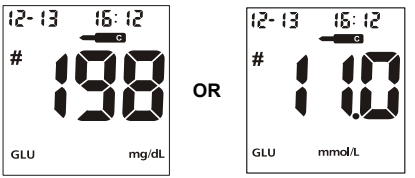




The blood glucose test results are displayed either in mmol/L or mg/dL depending on the unit of measure most common in your country.

Note: The glucose control solution range is the expected range for the glucose control solution test results. It is not a recommended range for a blood glucose level.

7. Slide the strip ejector to discard the test strip. The display should also show a pound sign (#) and "GLU" symbol indicating the test is a glucose control solution test. This shows that the number will not be counted in the 7, 14, 30, 60 and 90-day blood glucose averages. The pound sign (#) will also be displayed when reviewing the results stored in memory.



If the result falls outside the indicated control range:

- Confirm you are matching the correct range. Control Solution 1 results should be matched to the CTRL 1 range printed on the test strip vial (or on foil pouch).
- Check the expiration date of the test strip and control solution. Make sure that the test strip vial and control solution bottle have not been opened for more than 6 months. Discard any test strips or control solution that has expired.
- Confirm the temperature in which you are testing is between 10 and 40°C (50-104°F).
- Make sure that the test strip vial and control solution bottle have been tightly capped.
- Confirm that you are using the same brand of the glucose control solution and the blood glucose test strips.
- Make sure the code number on the strip vial label or foil pouch matches the code number that appears on the meter display.
- Make sure that you followed the test procedure correctly.

After checking all of the conditions listed above, repeat the glucose quality control test with a new blood glucose test strip. If your results still fall outside of the control range shown on the test strip vial (or on the foil pouch), your meter may be defective. Contact your local distributor for help.

Each of the Go-Keto Glucose Control Solution has three levels available. They are labeled Control Solution 0, Control Solution 1 and Control Solution 2. Control

Solution 1 is sufficient for most all self-testing needs. If you think your meter or strips may not be working properly, you may also want to do a level 0 or level 2 test. The ranges for CTRL 0, CTRL 1 and CTRL 2 are displayed on the test strip vial (or on the foil pouch). Simply repeat step 4 through 6, using Control Solution 0 or Control Solution 2.

For confirmation of results, Control Solution 0 tests should fall within the CTRL 0 range, Control Solution 1 tests should fall within the CTRL 1 range and Control Solution 2 tests should fall within the CTRL 2 range. If the control solution test results do not fall within the respective ranges, DO NOT use the system to test you blood glucose, as the system may not be working properly. If you cannot fix the problem, contact your local distributor for help.

Please contact your local distributor for information on ordering the different Go-Keto Glucose Control Solution kits.

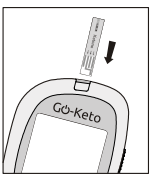
Ketone Quality Control Test

The Go-Keto Ketone Control Solution can be used for a ketone quality control test.

You should run a ketone quality control test:

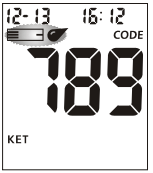
- Before you first use your meter to test blood β-ketone, to familiarize yourself with its operation.
- Before using a new box of Go-Keto Blood Ketone Test Strips.
- When you suspect that the Go-Keto Blood Glucose & Ketone Meter or Go-Keto Blood Ketone Test Strips are not working properly.
- When you suspect that your blood β-ketone test results are inaccurate, or if they are inconsistent with how you feel.
- When you suspect your meter is damaged.
- After cleaning your meter.

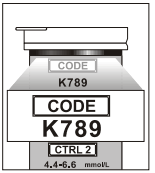
1. Insert a blood ketone test strip into the strip port, contact bars end first and facing up. (Insert the strip in as far as it will go without forcing.) This will turn on the meter and display all the display segments. If the audio option is on, the meter will beep, signaling the meter is turned on.





2. Check the display to confirm that all the display segments turn on (see display illustration above).
3. Following this display check, the system will enter the test mode. The display will show the date, time and the strip icon with the blood sample icon blinking. The code number and “KET” symbol will be displayed in the center of the screen. Make sure that the code number that appears on the display matches the code number (CODE) on the blood ketone test strip vial (or on foil pouch). If not, make sure to locate and insert the code chip that came with the box of blood ketone test strips. Do not perform a blood β-ketone test if the codes still do not match. You will need a new package of blood ketone test strips to perform a test.

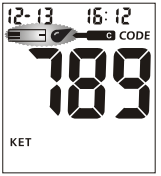




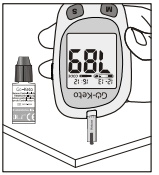
The blinking test strip and blood drop icon indicates that the test strip is inserted correctly.

Note: If the test strip has been inserted incorrectly, the meter will not turn on.

4. Press the M button to mark the test as a control solution test. Once the M button is pressed, the control solution symbol will appear on the display. Then a drop of ketone control solution can be added.



5. Shake the ketone control solution bottle well, then squeeze it gently and discard the first drop. If the tip clogs, tap the tip gently on a clean, hard surface, then shake again and use. Squeeze out a second small drop on a clean nonabsorbent surface. Touch the sample tip of the test strip to the control solution drop. If the audio option is turned on, the meter will beep indicating a test has been started.

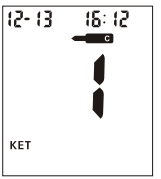


Note:

- Do not apply control solution to the test strip directly from the bottle.
- If you applied the control solution sample but do not see the starting of the count down, you may reapply a second drop within 3 seconds.

6. Once a sufficient sample has been applied, then the meter display will count down from 9 to 1 and then display the blood β-ketone test result. The ketone control solution test results should be within the β-ketone control range printed on the blood ketone test strip vial (or on foil pouch). This means that your meter and blood ketone test strips are working together properly and that you are performing the procedure correctly.

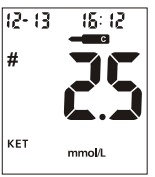




The blood β-ketone test results are displayed only in mmol/L.

Note: The ketone control solution range is the expected range for the ketone control solution results. It is not a recommended range for a blood β-ketone level.

7. Slide the strip ejector to discard the test strip. The display should also show a pound sign (#) indicating the test is a ketone control solution test. The pound sign (#) will also be displayed when reviewing the results stored in memory.



If the result falls outside the indicated control range:

- Confirm you are matching the correct range. Control Solution 1 results should be matched to the CTRL 1 range printed on the test strip vial (or on foil pouch).
- Check the expiration date of the test strip and control solution. Make sure that the test strip vial and control solution bottle have not been opened for more than 6 months. Discard any test strips or control solution that has expired.
- Confirm the temperature in which you are testing is between 10 and 40°C (50-104°F).
- Make sure that the test strip vial and control solution bottle have been tightly capped.
- Confirm that you are using the Go-Keto Ketone Control Solution that was provided with your kit.
- Make sure the code number on the strip vial label or foil pouch matches the code number that appears on the meter display.
- Make sure that you followed the test procedure correctly.

After checking all of the conditions listed above, repeat the ketone quality control test with a new blood ketone test strip. If your results still fall outside of the control range shown on the test strip vial (or on the foil pouch), your meter may be defective. Contact your local distributor for help.

Three levels of Go-Keto Ketone Control solution are available labeled Control Solution 0, Control Solution 1 and Control Solution 2. Control Solution 1 is sufficient for most all self-testing needs. If you think your meter or strips may not be working properly, you may also want to do a level 0 or level 2 test. The ranges for CTRL 0, CTRL 1 and CTRL 2 are displayed on the test strip vial (or on the foil pouch). Simply repeat step 4 through 6, using Control Solution 0 or Control Solution 2.

For confirmation of results, Control Solution 0 tests should fall within the CTRL 0 range, Control Solution 1 tests should fall within the CTRL 1 range and Control Solution 2 tests should fall within the CTRL 2 range. If the control solution test results do not fall within the respective ranges, DO NOT use the system to test you blood β-ketone, as the system may not be working properly. If you cannot fix the problem, contact your local distributor for help.

Please contact your local distributor for information on ordering the Go-Keto Ketone Control solution kit, which contains Control Solution 0, Control Solution 1 and Control Solution 2.

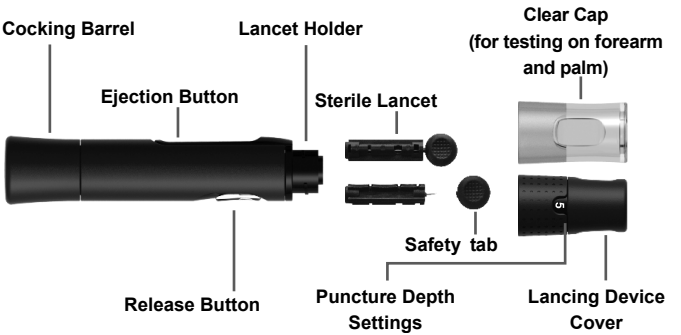
Testing Your Blood Glucose

The following steps will show how to use the Go-Keto Blood Glucose & Ketone Meter, Go-Keto Blood Glucose test strips, lancing device and sterile lancets together to measure your blood glucose concentration.

Step 1 – Getting a Drop of Blood

The blood glucose test requires a very small drop of blood which may be obtained from the fingertip, palm (at base of the thumb) or forearm. Before testing, choose a clean, dry work surface. Familiarize yourself with the procedure and make sure you have all the items needed to obtain a drop of blood.

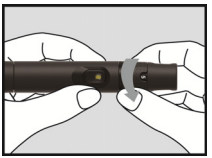
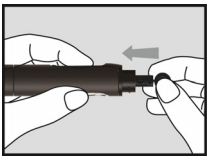
IMPORTANT: Prior to testing, wipe the test site with an alcohol swab or soapy water. Use warm water to increase blood flow if necessary. Then dry your hands and the test site thoroughly. Make sure there is no alcohol, soap, cream or lotion on the test site.



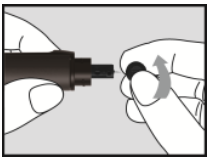
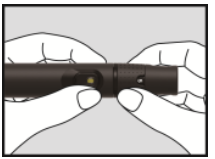
Fingertip Sampling

For fingertip sampling, adjust the depth penetration to reduce the discomfort. You do not need the clear cap for fingertip sampling.

1. Unscrew the lancing device cover from the body of the lancing device. Insert a sterile lancet into the lancing device and push it until the lancet comes to a complete stop in the lancing device.

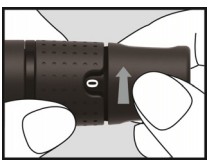



2. Hold the lancet firmly in the lancing device and twist the safety tab of the lancet until it loosens. Then pull the safety tab off the lancet. Save the safety tab for lancet disposal.
3. Carefully screw the cover back onto the lancing device. Avoid contact with the exposed needle. Make sure the cover is fully sealed on the lancing device.

4. Adjust the puncture depth by rotating the lancing device cover. There are a total of 11 puncture depth settings. To reduce the discomfort, use the lowest setting that still produces an adequate drop of blood.



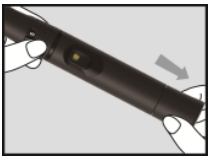


Adjustments:

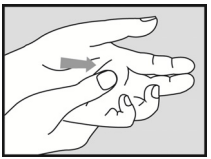
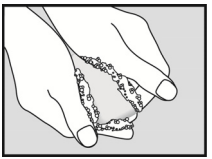
0 - 1.5 for delicate skin
2 - 3.5 for normal skin
4 - 5 for calloused or thick skin

Note: *Increase pressure of the lancing device against the finger will also increase the puncture depth.*

5. Pull the cocking barrel back to set the lancing device. You may hear a click while the release button changes to orange to indicate the lancing device is now loaded and ready for obtaining a drop of blood.

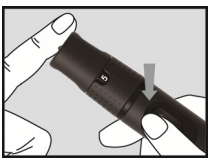
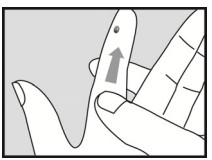


6. Prior to testing, clean your hands with an alcohol wipe or wash your hands with soap. Use warm water to increase blood flow in your fingers if necessary. Then dry your hands thoroughly. Massage the hand from the wrist up to the fingertip a few times to encourage blood flow.

7. Hold the lancing device against the side of the finger to be lanced with the cover resting on the finger. Push the release button to prick your fingertip. You should hear a click as the lancing device activates. Gently massage your finger from the base of the finger to the tip of the finger to obtain the required blood volume. Avoid smearing the drop of blood.

   For the greatest reduction in pain, lance on the sides of the fingertips. Rotation of sites is recommended. Repeated punctures in the same spot can make your fingers sore and callused.

Forearm and Palm Sampling

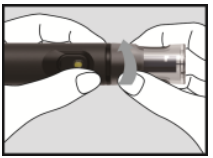
The forearm and palm areas have less nerve endings than the fingertip. You may find that obtaining blood from these sites is less painful than from the fingertip. The procedure for forearm and palm sampling is different. You need the clear cap to draw blood from these sites. The clear cap is not adjustable for puncture depth.

IMPORTANT: There are important differences among forearm, palm and fingertip samples that you should know. Important Information about forearm and palm glucose testing:

- You should consult your healthcare professional before choosing to perform forearm or palm testing.
- When blood levels are changing rapidly such as after a meal, insulin dose or exercise, blood from the fingertips may show these changes more rapidly than blood from other areas.
- Fingertips should be used if testing is within 2 hours of a meal, insulin dose or exercise and any time you feel glucose levels are changing rapidly.
- You should test with the fingertips anytime there is a concern for hypoglycemia or you suffer from hypoglycemia unawareness.

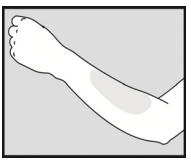
Please refer to **Fingertip Sampling** to insert the lancet and load the lancing device.

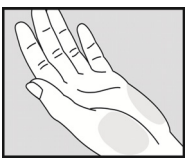
1. Screw the clear cap onto the lancing device.



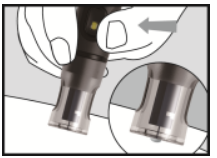
2. Choose a puncture site on the forearm or palm. Select a soft and fleshy area of the forearm and palm that is clean and dry, away from bone, and free of visible veins and hair.

   To bring fresh blood to the surface of the puncture site, massage the puncture site vigorously for a few seconds until you feel it getting warm.



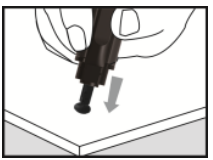


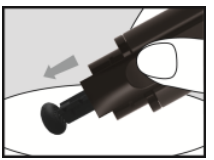
3. Place the lancing device against the puncture site. Press and hold the clear cap against the puncture site for a few seconds. Press the release button of the lancing device, but **do not immediately lift the lancing device** from the puncture site. Continue to hold the lancing device against the puncture site until you can confirm a sufficient blood sample has formed.



Disposal of the Lancet

1. Unscrew the lancing device cover. Place the safety tab of the lancet on a hard surface. Then carefully insert the lancet needle into the safety tab.
2. Press the release button to make sure that the lancet is in the extended position. Slide the ejection button forward to discard the used lancet. Place the lancing device cover back on the lancing device.





Lancet Precautions

- Do not use the lancet if the safety tab is missing or loose when you take the lancet out of the bag.
- Do not use the lancet if the needle is bent.
- Use with caution whenever the lancet needle is exposed.
- Never share lancets or the lancing device with other people.
- In order to reduce the risk of infection from prior use of the instrument, always use a new, sterile lancet. Do not reuse lancets.
- Avoid getting the lancing device or lancets dirty with hand lotion, oils, dirt or debris.

Specimen collection and preparation by healthcare professionals

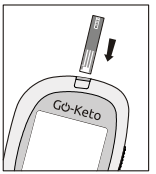
- A small drop of fresh whole blood is needed to perform the blood glucose test. Do not use serum or plasma samples. The Go-Keto Blood Glucose Test Strips are for testing fresh capillary and neonatal whole blood.
- Venous, arterial or neonatal blood samples should be drawn only by healthcare professionals. When collecting any type of sample, professionals need to follow universal blood collection precautions and guidelines.
- Venous or arterial blood samples in heparin and EDTA anticoagulants/ preservatives may be used. Do not use anticoagulants such as iodoacetate, sodium citrate, or those containing fluoride.
- Always test the blood sample as close as possible to the time the sample is collected. Otherwise, the venous or arterial blood glucose measurement should be performed within 15 minutes of blood sample collection to minimize the effect of glycolysis.
- When whole blood in a test tube is used, care should be taken to uniformly distribute red cells throughout the tube before testing. Gently invert the capped tube several times. (Please note do not mix the blood sample in the tube too much.)
- Neonatal blood sample may be collected from the heel using a single-use lancing device.
- The system has been tested with neonatal blood (capillary from heel). As a matter of good clinical practice, caution is advised in the interpretation of neonate glucose values below 50 mg/dL. Please follow the recommendations for follow-up care that have been set by your institution for critical glucose values in neonates. Results for neonates exhibiting symptoms of galactosemia should be confirmed by laboratory tests.

Please refer to the Go-Keto Blood Glucose Test Strips insert for more information.

Step 2 – Testing Blood Glucose

Note: **Insertion of a new test strip at any time, except while in the data transfer mode (detailed on page 55), will cause the meter to automatically enter the test mode.**

1. Insert a blood glucose test strip into the strip port, contact bars end first and facing up, to turn on the meter and display all the display segments. If the audio option is on, the meter will beep, signaling the meter is turned on.





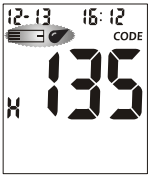
2. Check the display to confirm that all the display segments turn on (see display illustration).
3. Following this display check, the system will enter the test mode. The display will show the date, time and the strip icon with the blood sample icon blinking. The code type and code number will be displayed in the center of the screen.

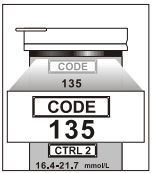


Compare the code type letter before the code number on the display with the brand of the strip inserted in the meter. “H” is for a Go-Keto Blood Glucose Test Strip. If the code type on the display does not match the brand of the strip inserted in the meter, please make sure to locate and insert the correct code chip that came with the box of blood glucose test strips.

Make sure that the code number that appears on the display matches the code number (CODE) on the test strip vial (or on foil pouch). If not, make sure to locate and insert the code chip that came with the box of blood glucose test strips. If the codes still do not match, do not perform a test. You will need a new package of test strips to perform a test.





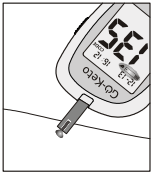


4. The blinking test strip and blood drop icon will indicate that the test strip is inserted correctly and a drop of blood can be added. The meter will not turn on if the test strip has been inserted incorrectly.
5. Touch the blood sample to the sample tip at the end of the test strip. If the audio option is turned on, the meter will also beep to indicate the measurement has started. If you applied a drop of blood but do not see the starting of the countdown, you may reapply a second drop of blood within 3 seconds.

   DO NOT:

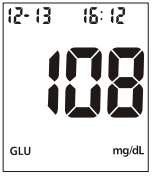
   - Apply sample to the front or back of the test strip.
   - Smear the blood drop onto the test strip.
   - Press your finger against the test strip.



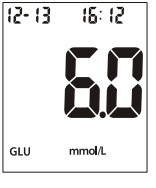


6. The meter will count down from 5 to 1 and then display the measurement results. The meter will also beep to indicate that measurement is complete. Then your blood glucose level will display on the screen, along with the “GLU” symbol, unit measurement, date, and time of the test.





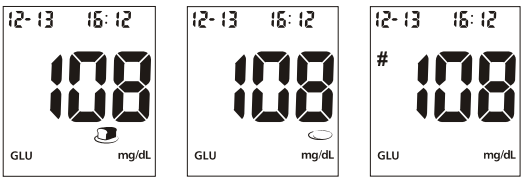
OR



Blood glucose results are automatically stored in the memory. To mark invalid results and prevent them from being included in the 7, 14, 30, 60 and 90-day averages, press the M and S buttons together. A pound sign (#) will appear on the display to show that the blood glucose test result will not be included when calculating the 7, 14, 30, 60 and 90-day averages. If a blood glucose result is marked by accident, press the M button to unmark the result. After marking the invalid blood glucose result with a pound sign (#), press the S button to confirm the invalid blood glucose result.

When the meal marker feature is turned on and a blood glucose test result is displayed, mark the blood glucose result as “before meal”, “after meal”, or invalid.

- Press the M and S buttons together to display the “before meal marker” symbol, indicating the blood glucose result was taken before a meal.
- Press the M button again to display the “after meal marker” symbol, indicating the blood glucose result was taken after a meal.
- Press the M button again to display the pound sign (#), indicating an invalid blood glucose result.
- Press the M button again then none of the above markers will be displayed for the blood glucose result.

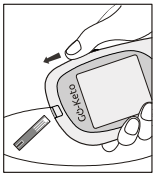


After deciding the selection, press the S button to confirm the selection for “before meal marker”, “after meal marker”, “invalid result pound sign” or none of these three symbols. If an invalid blood glucose result is marked, run the blood glucose test again with a new blood glucose test strip.

If an error message appears on the display, refer to the **Troubleshooting Guide** on page **62**. If a "HI" or "LO" appears on the display, refer to "HI" and "LO" messages below.

7. After inspection, record valid blood glucose results in your logbook with the date and time. Then compare them to the blood glucose target goals set by your healthcare professional. Refer to **Suggested Testing Times and blood glucose Target Goals** on page **59** for more details on your target blood glucose concentration goals.

8. Slide forward the strip ejector to discard the used test strip.



Note: Dispose of blood samples and materials carefully. Treat all blood samples as if they are infectious materials. Follow proper precautions and obey all local rules when disposing of blood samples and materials.

"HI" and "LO" Messages

The meter can accurately measure blood glucose concentrations between 0.6 and 33.3 mmol/L (10-600 mg/dL). "HI" and "LO" messages indicate blood glucose results outside of this range.

If "HI" appears on the display, the measured blood glucose concentration value is above 33.3 mmol/L (600 mg/dL). The test should be retaken to ensure that no mistake was made in the procedure. If you are certain the meter is functioning properly and no mistakes were made in the procedure, and your blood glucose is still consistently measured as "HI", it indicates severe hyperglycemia (high blood glucose). You should contact your healthcare professional immediately.

If "LO" appears on the display, the measured blood glucose concentration value is below 0.6 mmol/L (10 mg/dL). The test should be retaken to ensure that no mistake was made in the procedure. If you are certain the meter is functioning properly and no mistakes were made in the procedure, and your blood glucose is still consistently measured as "LO", it may indicate severe hypoglycemia (low blood glucose). You should treat yourself for hypoglycemia immediately as recommended by your healthcare professional.



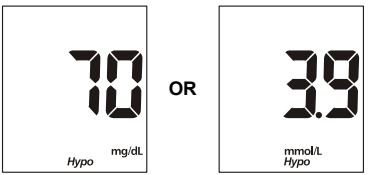


"Hypo" and "Hyper" Messages

Note: "Hypo" and "Hyper" Messages will only appear when testing blood glucose.

If “Hypo” appears on the display, the measured blood glucose concentration value is below the “Hypo” (low blood sugar) target level that you have set.

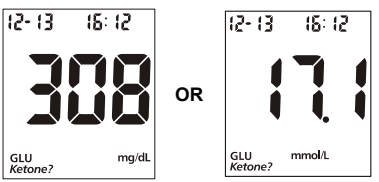
If “Hyper” appears on the display, the measured blood glucose concentration value is above the “Hyper” (high blood sugar) target level that you have set.



"Ketone?" Message

Note: "Ketone?" Messages will only appear when testing blood glucose.

If “Ketone?” appears on the display, the measured blood glucose concentration value is above 16.7 mmol/L (300 mg/dL). A ketone test is recommended when the “Ketone?” symbol appears.



You can perform a ketone test with our Go-Keto Blood Ketone Test Strips. Consult your local distributor for ordering the Go-Keto Blood Ketone Test Strips kit.

Precautions and Limitations for Blood Glucose Testing

Please refer to the Go-Keto Blood Glucose Test Strips insert for more information.

Testing Your Blood Ketone

The following steps will show how to use the Go-Keto Blood Glucose & Ketone Meter, Go-Keto Blood Ketone test strips, lancing device and sterile lancets together to measure your blood β-ketone concentration.

Step 1 – Getting a Drop of Blood

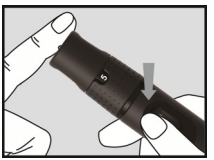
CAUTION: β-ketone testing must not use the forearm or palm site. Only use the fingertip for β-ketone testing.

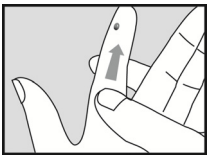
The blood β-ketone test requires a very small drop of blood. Before testing, choose a clean, dry work surface. Familiarize yourself with the procedure and make sure you have all the items needed to obtain a drop of blood.

IMPORTANT: Prior to testing, wipe the test site with an alcohol swab or soapy water. Use warm water to increase blood flow if necessary. Then dry your hands and the test site thoroughly. Make sure there is no alcohol, soap, cream or lotion on the test site.

Fingertip Sampling

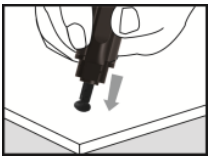
Please refer to **Fingertip Sampling** in **Getting a Drop of Blood** for testing your blood glucose on page **35** to get a drop pf blood from your fingertip for blood β-ketone testing.

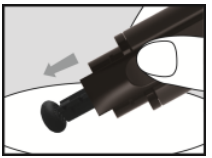




Disposal of the Lancet

1. Unscrew the lancing device cover. Place the safety tab of the lancet on a hard surface. Then carefully insert the lancet needle into the safety tab.
2. Press the release button to make sure that the lancet is in the extended position. Slide the ejection button forward to discard the used lancet. Place the lancing device cover back on the lancing device.





Lancet Precautions

- Do not use the lancet if the safety tab is missing or loose when you take the lancet out of the bag.
- Do not use the lancet if the needle is bent.
- Use with caution whenever the lancet needle is exposed.
- Never share lancets or the lancing device with other people.
- In order to reduce the risk of infection from prior use of the instrument, always use a new, sterile lancet. Do not reuse lancets.
- Avoid getting the lancing device or lancets dirty with hand lotion, oils, dirt or debris.

Specimen collection and preparation by healthcare professionals

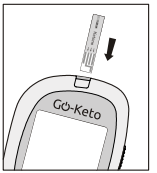
- A small drop of fresh whole blood is needed to perform the blood ketone test. Do not use serum or plasma samples. The Go-Keto Blood Ketone Test Strips are for testing fresh capillary and venous whole blood.
- Venous blood samples should be drawn only by healthcare professionals. When collecting sample, professionals need to follow universal blood collection precautions and guidelines.
- Venous samples in heparin or EDTA anticoagulants/preservatives may be used. Do not use anticoagulants such as iodoacetate, sodium citrate, or those containing fluoride.
- Always test the blood sample as close as possible to the time the sample is collected.
- When whole blood in a test tube is used, care should be taken to uniformly distribute red cells throughout the tube before testing. Gently invert the capped tube several times. (Please note do not mix the blood sample in the tube too much.)

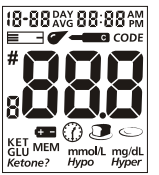
Please refer to the Go-Keto Blood Ketone Test Strips insert for more information.

Step 2 – Testing Blood Ketone

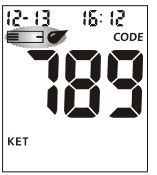
Note: **Insertion of a new blood ketone test strip at any time, except while in the data transfer mode (detailed on page 55), will cause the meter to automatically enter the test mode.**

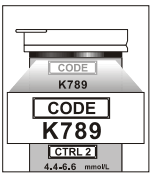
1. Insert a blood ketone test strip into the strip port, contact bars end first and facing up, to turn on the meter and display all the display segments. If the audio option is on, the meter will beep, signaling the meter is turned on.





2. Check the display to confirm that all the display segments turn on (see display illustration).
3. Following this display check, the system will enter the test mode. The display will show the date, time and the strip icon with the blood sample icon blinking. The code number and “KET” symbol will be displayed in the center of the screen. Make sure that the code number appears on the display matches the code number (CODE) on the blood ketone test strip vial (or on foil pouch). If not, make sure to locate and insert the code chip that came with the box of blood ketone test strips. If the codes still do not match, do not perform a test. You will need a new package of blood ketone test strips to perform a blood ketone test.





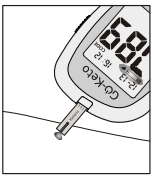
4. The blinking test strip and blood drop icon will indicate that the test strip is inserted correctly and a drop of blood can be added. The meter will not turn on if the test strip has been inserted incorrectly.

5. Touch the blood sample to the sample tip at the end of the test strip. If the audio option is turned on, the meter will also beep to indicate the measurement has started. If you applied a drop of blood but do not see the starting of the countdown, you may reapply a second drop of blood within 3 seconds.

   DO NOT:

   - Apply sample to the front or back of the test strip.
   - Smear the blood drop onto the test strip.
   - Press your finger against the test strip.

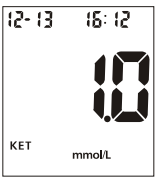




6. The meter will count down from 9 to 1 and then display the blood β-ketone test results. The meter will also beep to indicate that measurement is complete. Then your blood β-ketone level will display on the screen, along with the unit measurement, date, and time of the test. The test blood β-ketone results are automatically stored in the memory.







   If an error message appears on the display, refer to the **Troubleshooting Guide** on page **62**. If a "HI" appears on the display, refer to "HI" messages below.

7. Slide forward the strip ejector to discard the used test strip.

   Note: Dispose of blood samples and materials carefully. Treat all blood samples as if they are infectious materials. Follow proper precautions and obey all local rules when disposing of blood samples and materials.



"HI" Message

The meter can accurately measure blood β-ketone concentrations between 0 and 8.0 mmol/L. "HI" message indicate results outside of this range.

If "HI" appears on the display, the measured β-ketone concentration value is above 8.0 mmol/L. The test should be retaken to ensure that no mistake was made in the procedure. If you are certain the meter is functioning properly and no mistakes were made in the procedure, and your blood β-ketone is still consistently measured as "HI", you should contact your healthcare professional immediately.



Precautions and Limitations for Blood Ketone Testing

Please refer to the Go-Keto Blood Ketone Test Strips insert for more information.

Using the Meter Memory

The meter automatically stores up to 450 blood glucose and β-ketone test records. Each record includes the test result, result type, date and time. The oldest record will be erased to make room for a new one if there are already 450 records in memory.

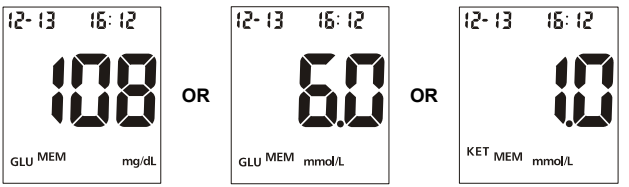
The meter will also calculate the blood glucose average values of the blood glucose records from the last 7, 14, 30, 60 and 90 days.

Note: All the blood β-ketone test results are not caculated in the 7, 14, 30, 60 and 90-day averages. Only glucose test results are averaged.

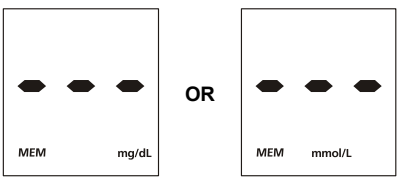
Viewing Stored Records

To view stored records:

1. Press the M button to turn the meter on and enter memory mode. The most recent value with the result type “GLU” or “KET” and the symbol "MEM" will appear on the display.



2. If you are using the meter for the very first time, the meter display will show three dashed lines (---), the symbol "MEM" and the unit of measure. This shows that no data have been stored in memory.



3. The date and time will be displayed together with the results stored in memory. A pound sign (#) in blood glucose test results indicates that the records will be omitted from the 7, 14, 30, 60 and 90-day blood glucose averages.

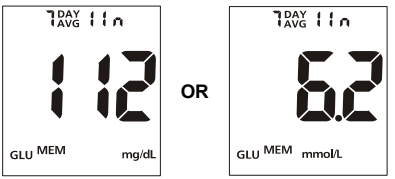
4. Press the M button to go through the stored records.

   Press the S button to view the blood glucose averages. The words "DAY AVG" will appear on the screen.
   Note: If you do not wish to view your average glucose measurements, you can press the S button again to turn off the display.

5. While in data average mode:

   - If the meal marker feature is off, press the M button to switch between the general 7, 14, 30, 60 and 90-day blood glucose averages.
   - If the meal marker feature is on, press the M button to switch between the general, pre-meal and post-meal 7, 14, 30, 60 and 90-day blood glucose averages. The meter will calculate the average that you selected. The number of records used in the DAY AVG will also appear in the display.

     Note: Only blood glucose test results that have been marked as "before meal" or "after meal" are included in pre-meal and post-meal averages. All blood glucose results are included in the general 7, 14, 30, 60 and 90-day averages.



6. If there are fewer than 7, 14, 30, 60 and 90-days in memory, all the blood glucose readings without the pound sign (#) currently stored in memory will be averaged instead.

   If you are using the meter for the very first time, no value will appear on the display. This means that no records have been stored in memory. If you have not marked any results as "before meal" or "after meal", no value will appear on the display for the pre-meal or post-meal averages. This means that no records have been stored as "before meal" or "after meal" in memory.

7. Press the S button to turn off the display.

   Note: Results from quality control tests will not be included in the averages. When viewing results in memory, these values are marked with a pound sign (#) to show that they will not be included in the 7, 14, 30, 60 and 90-day blood glucose averages.

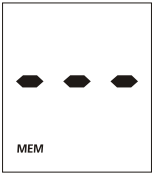
Clearing the Memory

Extreme caution should be used when clearing the memory. This is not a reversible operation. To clear the memory:

1. With the meter off, press and hold the M button for two seconds. This will turn on the meter and enter the delete mode.



2. Then press and hold both the M and S buttons for two seconds to clear the memory.
3. The display will show "MEM" and "---", the meter will clear its memory and turn itself off after a moment.



4. If you entered the delete mode but want to exit without deleting the recorded data, press the S button. This will turn the meter off without deleting any data.

Transferring Records

The meter can transfer stored information to a Windows-based personal computer (PC) using an optional data transfer cable and software package. To make use of this feature, you need the Diabetes Management Software and a USB data transfer cable from ***ACON***.

1. Install the software to your personal computer (PC) according to the instructions from the Diabetes Management Software Kit.
2. Connect the USB cable to your PC and plug the audio jack of the cable into the meter data port. Meter automatically enters “PC” mode.

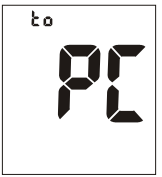
Notes:

- When strip is already inserted into the meter and meter is in the waiting for sample application mode, at this point if data transfer cable is plugged into meter data port then meter gives E-12 error message and does not automatically turn to “PC” mode.
- When meter is in “PC” mode, meter does not turn to waiting for sample application mode after strip is inserted into meter.





3. Run the Diabetes Management Software, and refer to the instructions from the software for how to transfer records.
4. During the data transfer, the meter will display “to” and “PC”. This indicates the data is being transferred from the meter to the PC.
5. Once the data transfer is complete, the meter will display “End” and “PC”.





6. After data transfer from meter to PC is completed, press the S button to turn off the meter. If nothing else happens to meter 2 minutes after data transfer from meter to PC is completed, the meter will automatically turn off. In this case press the M and S buttons together to enter “PC” mode again.

Note: Peripheral equipment such as computer which is intended to be connected with meter shall conform to relevant safety standard.

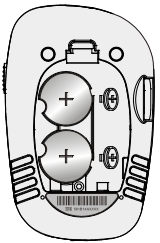
See the package insert included with your Diabetes Management Software Kit for detailed instructions.

Maintenance

Proper maintenance is recommended for best results.

Replacing the Battery

When the battery icon () is blinking, it means the battery is running low and you should replace the battery as soon as possible. An "E-6" error message will appear if the battery is too low to perform any more blood glucose tests. The meter will not function until the battery is replaced.



Instructions:

1. Make sure the meter is off before removing the battery.
2. Turn over the meter to locate the battery cover. Press the battery cover tab on the top and lift the cover to open the battery cover.
3. Remove and discard the old battery. Insert two new CR 2032 3.0V coin cell batteries on top of plastic tape. Make sure it is aligned with the plus (+) side facing up in the battery carrier.
4. Close the battery cover and make sure that it snaps shut.
5. Recheck and reset the clock setting as necessary after battery replacement to ensure time is set correctly. To set the meter clock, see **Meter Setup Before Testing** on page **20**.

Caring for Your Go-Keto Blood Glucose & Ketone Monitoring System

Blood Glucose & Ketone Meter

Your Go-Keto Blood Glucose & Ketone Meter does not require special maintenance or cleaning. A cloth dampened with water and a mild detergent solution can be used to wipe the outside of the meter. Take care to avoid getting liquids, dirt, blood or control solution into the meter through the strip or data ports. It is recommended that you store the meter in the carrying case after each use.
Go-Keto Blood Glucose & Ketone Meter is a precision electronic instrument. Please handle it with care.

Lancing Device

Use mild soap and warm water to clean with a soft cloth as required. Carefully dry the device thoroughly. Do not immerse the lancing device.
Please refer to the lancing device insert for more details.

Suggestion and Reference

Suggested Blood Glucose Testing Time and Target Goals

Tracking your blood glucose concentration through frequent testing is an important part of proper diabetes care. Your healthcare professional will help you to decide the normal target range for your glucose levels. They will also help you determine when and how often to test your blood glucose. Some suggested times are:

- When you wake up (fasting level)
- Before breakfast
- 1-2 hours after breakfast
- Before lunch
- 1-2 hours after lunch
- Before or after exercise
- Before dinner
- 1-2 hours after dinner
- Before bedtime
- After a snack
- At 2 or 3 AM, if taking insulin

You may need to test more often whenever[1]:

- You add or adjust your medication for diabetes.
- You think your blood glucose levels may be too low or too high.
- You are ill, or feeling uncomfortable over long periods of time.

Expect blood glucose levels for people without diabetes[2]:

Time	Range, mg/dL	Range, mmol/L
Fasting and Before Meals	70-100	3.9-5.6
2 Hours after Meals	Less than 140	Less than 7.8

Talk to your healthcare professional to set your own daily blood glucose target ranges.

Time of Day	Your Target Range
Waking up (Fasting level)	
Before meals	
2 hours after meals	
Bedtime	
2 AM to 3 AM	
Other	

(Note: 1 mmol/L = 18 mg/dL)

Use the logbook to record your blood glucose measurements and related information. Bring the logbook with you when visiting your doctor so that you can determine how well your blood glucose is being controlled. This can help you and your healthcare professional make the best decisions about your glucose control plan.

Reference for Your β-Ketone Test Results

The normal adult blood β-ketone range for person without diabetes is less than 0.6 mmol/L. Consult with your healthcare professional for the blood β-ketone range that is appropriate for you.

If your blood β-ketone test result is between 0.6-1.5 mmol/L and glucose is higher than 300 mg/dL, this may indicate development of a medical concern. You need to contact with your healthcare professional for assistance.

If your blood β-ketone test result is more than 1.5 mmol/L and glucose is higher than 300 mg/dL, contact with your healthcare professional immediately. This indicates a risk of developing diabetic ketoacidosis (DKA).

1. Jennifer Mayfield and Stephen Havas, “Self-Control: A Physician’s Guide to Blood Glucose Monitoring in the Management of Diabetes – An American Family Physician Monograph”
2. ADA, Standards of Medical Care in Diabetes-2021

Comparing Meter and Laboratory Results

Your Go-Keto Blood Glucose & Ketone Monitoring System and laboratory results both report the glucose or β-ketone concentration in the serum or plasma component of your blood. However, the results may differ somewhat due to normal variation. This is expected, but the difference under normal operating conditions should be no greater than 20%. See the test strip package inserts for typical accuracy and precision data. To ensure a reasonable comparison, follow these guidelines.

Before you go to the lab:

- Bring your meter, test strip and control solution with you to the lab.
- Make sure your meter is clean.
- Perform a quality control test to make sure the meter is working properly.
- Comparisons will be more accurate if you do not eat for at least four hours (preferably eight hours) before blood glucose testing.

At the lab:

- Wash your hands before obtaining a blood sample.
- Obtain blood samples for a laboratory test and for your meter within 10 minutes of each other. This will ensure an accurate comparison of results.
- Never use your meter with blood that has been placed in test tubes containing fluoride or other anticoagulants which are not suggested. This will cause falsely low results.

Troubleshooting Guide

The meter has built-in messages to alert you of problems. When error messages appear, note the error number, turn off the meter and then follow these instructions.

Display	Causes	Solution
Meter fails to turn on	Battery may be damaged or not be charged	Replace battery.
	Meter is too cold	If meter has been exposed to or stored in cold conditions, wait 30 minutes to allow meter to reach room temperature then repeat test.
	Power On self check error	Remove battery for 30 seconds and then put battery back and turn meter on again. If problem persists, please contact your local distributor.
	Internal calibration check error	Turn off meter or remove test strip, and then turn on meter again to retest.If the problem persists, please contact your local distributor.
	Test strip was removed during the test	Repeat the test and ensure test strip remains in place.
	Sample was applied to the test strip too soon	Repeat test and apply sample after blood drop/test strip symbol appears.
	Test strip is contaminated or used	Repeat test with a new test strip.
	Insufficient sample	Repeat test and apply enough sample to fill the test strip check window.
	Sample application error due to late sample re-dosing	Repeat test and apply enough sample to fill the test strip check window within 3 seconds.
	Temperature has exceeded the operating temperature of the system	Move to a cooler environment and repeat the test.
	Temperature is below the operating temperature of the system	Move to a warmer environment and repeat the test.
	Battery is discharged but has enough power to run 20 more tests	Test results will still be accurate, but replace the battery as soon as possible.

Display	Causes	Solution
	Battery has discharged and meter does not allow more tests until discharged battery is replacement with a new battery	Replace the battery and repeat the test.
	No code chip in the meter	Insert the code chip that accompanied the box of test strips.
	Damaged code chip or the code chip was removed during a test	If the code chip is damaged, use a new code chip with the correct code number and run the test. If the code chip is removed during a test, confirm the code chip matches the test strip code and repeat the test.
	Meter electronics failure	If the problem persists, please contact your local distributor.
	Incorrect code chip inserted in the meter	Indicates an incorrect brand of code chip was inserted in the meter. Please make sure you use the Go-Keto Blood Glucose Test Strips to test glucose and use the Go-Keto Blood Ketone Test Strips to test β-ketone. If the problem persists, please contact your local distributor.
	Communications failure	There is an error in transferring data to the PC. See the package insert included with the Diabetes Management Software Kit for troubleshooting.
	Strip testing error	Repeat test and apply enough sample to fill the test strip check window within 3 seconds. When repeat testing, do not touch the strip during meter counts down. Please make sure fresh blood sample with intended hematocrit level is used. Please make sure blood sample is not contaminated. If the problem persists, please contact your local distributor.
	Meter data port is plugged in with data transfer cable when meter is in waiting for sample application mode with strip already inserted into the meter strip port	Unplug the data transfer cable from the meter's data port. Then remove the strip. Reinsert the strip into the strip port for testing. If the problem persists, please contact your local distributor.

Specifications

Feature	Specification
Meter Model Number	OGM - 161
Measurement Range	Glucose: 0.6 - 33.3 mmol/L (10 - 600 mg/dL) β-ketone: 0.0 - 8.0 mmol/L
Result Calibration	Plasma-equivalent
Sample	Please refer to the blood glucose and ketone test strip inserts
Minimum Sample Size	Glucose: 0.8 μL β-ketone: 1.2 μL
Test Time	Glucose: 5 seconds β-ketone: 10 seconds
On/Off Source	Two (2) CR 2032 3.0V coin cell batteries
Battery Life	Minimum of 3,000 measurements (without considering data transfer and test reminder alarm)
Measurement Unit	Glucose: The meter is pre-set to either mmol/L or mg/dL, depending on the standard of your country β-Ketone: The meter is pre-set to mmol/L
Memory	Up to 450 blood glucose and β-ketone records with result type, date and time
Automatic shutoff	2 minutes after last action
Meter Size	90.3 mm × 58.0 mm × 19.4 mm
Display Size	40.2 mm × 36.0 mm
Weight	64g (with battery installed)
Operation Environmental Conditions	Temperature: 5 - 45ºC(41 - 113°F); Relative Humidity: 10 - 90% (non-condensing); Altitude: ≤ 3048m
Meter Storage and Transportation Conditions	Temperature: -20 - 50°C(−4 - 122ºF); Relative humidity: 10 - 93% (non-condensing); Air pressure: 500 - 1060 hPa
Hematocrit Range	Please refer to the test strip inserts
Pollution Degree	2
Means of protection	Class III
Marked degree of protection	IPX0
Data Port	9600 baud, 8 data bits, 1 stop bit, no parity

Warranty

Please complete the warranty card that came with this product and mail it to your local distributor to register your purchase.

If the meter fails to work for any reason other than obvious abuse within the first five (5) years from purchase, we will replace it with a new meter free of charge. For your records, also write the purchase date of your product here.

Date of purchase: _____

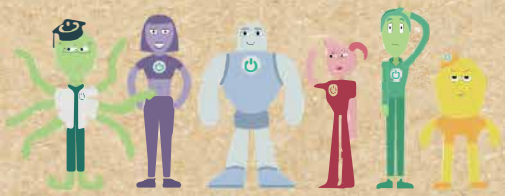
Note: This warranty applies only to the meter in the original purchase, and does not apply to the battery supplied with the meter.

Index of Symbols

	Consult instructions for use
IVD	*In vitro* diagnostic medical device
	Temperature limit -Glucose Strips & Control Solutions
	Temperature limit -Ketone Strips & Control Solutions
	Contains sufficient for <*n*> tests
	Use by
LOT	Lot Number
	Manufacturer
EC REP	Authorized representative in the European Community
STERILE R	Sterilized using irradiation
CTRL	Control Range
REF	Catalogue Number
SN	Serial Number
MODEL	Model Number
	Do not dispose along with household waste
	Humidity limitation
	Atmospheric pressure limitation
	Direct current
	Do not reuse

Index

Averaging Results..... **53**
Battery, Replacing the..... **57**
Carrying Case..... **1**
Clearing the Memory..... **55**
Data Port..... **4,5**
Date Format..... **10,13,17**
Guidelines..... **i**
Hematocrit..... **38**
Hyperglycemia..... **24,44**
Hypoglycemia..... **25,44**
Index..... **67**
Maintenance..... **8,57**
Measure, Unit of..... **8,30**
Meter..... **6**
Audio feature..... 23
Cleaning..... 58
Code chip..... 1,3,20
Display..... 6
Error Messages..... 62,63
"HI" and "LO" Messages..... 44
M Button..... 4,5
Memory..... 55
Meter code..... 20
Meter Use and Precautions.. 8
Meter Setup..... 20
S Button..... 4,5
Set the Clock..... 22
Specifications..... 64
Strip ejector..... 5,30,50
Procedure
Precautions and Limitations... 46,52
Testing Your Blood..... 35,47
Quality Control Test..... **27**
Glucose Control Solution..... 12,27
Ketone Control Solution..... 17,31
How to Run..... 27,31
Results
Blood Glucose..... 42
Blood β-Ketone..... 50
Glucose Control Solution..... 30
Ketone Control Solution..... 33
Meter vs. Lab Results..... 61
Reference for ketone results.. 60
Target Goals..... 59
Unit of Measure..... 30,53
Suggested Testing Times..... **59**
Test Strip..... **9,14**
Code..... 10,15
Expiration..... 10,15
Precautions..... 11,16
Testing Your Blood..... **20**
Get a Drop of Blood..... 35,47
Test Blood Glucose..... 41
Test Blood Ketone..... 49
Troubleshooting..... **62**
Viewing Stored Records..... **53**
Warranty..... **3,65**



Our team is here for you!

Need help on your Go-Keto journey?

Do you need help kick starting your Go-Keto journey?
Feel free to ask any questions or share your experiences.
We love to hear from you. Reach out to us!

Go-Keto

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